FDA Acknowledgement of Product Report

Accession number: 1611158-000 (CREMOTECH CO., LTD.)

Product: LASER BEAM PRO, SMART BEAM LASER

From : FDA Radiological Health Electronic Submission Program

This message is to acknowledge receipt of your **Initial Product Report** , which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (Title 21, Code of Federal Regulations, Subchapter J) as they pertain to the submission information description below. If your submission is a report, it has been filed according to reporting requirements in Title 21, Code of Federal Regulations (CFR), Part 1002. Your submission has been assigned an informal subject title below after "Purpose:". Your submission has been assigned an ACCESSION NUMBER which can be used by you and FDA to identify your submission

WARNING:
THE ACCESSION NUMBER ASSIGNED TO YOUR SUBMISSION DOES NOT IMPLY, CONVEY OR CONSTITUTE FDA APPROVAL OF ANY REPORT, APPLICATION FOR VARIANCE OR EXEMPTION, NOTIFICATION, OR ANY OTHER SUBMISSION OR ITS CONTENTS. THE ACCESSION NUMBER IS ONLY AN ACKNOWLEDGMENT THAT FDA HAS RECEIVED YOUR SUBMISSION. IT MAY BE REVOKED BY FDA. ITS DISCLOSURE IS YOUR RESPONSIBILITY. IT IDENTIFIES YOUR SUBMISSION FOR PRODUCTS OR PRODUCT FAMILIES IDENTIFIED IN THIS MESSAGE.

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Accession Number:	**1611158-000**
Date Loaded:	**DEC 19, 2016**
Document Date:	**DEC 19, 2016**
Establishment Name:	**CREMOTECH CO., LTD.**

Purpose: This submission is a(n) Initial Product Report. These Laser Light Show/Display Products include designated Smart Beam LaserLaser Beam Pro.

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Please note that your firm is required to submit an Annual Report to CDRH every year by September 1.

If you meet all other applicable FDA requirements, you may market the product(s) reported. Please be aware that additional electronic product radiation control or medical device regulations may apply to your product, such as:

21 CFR 1002.11, requiring report supplements under certain circumstances following the same reporting forms as used for product reports on your products
21 CFR 1002.13, requiring annual reports to be submitted each year by September 1 using the appropriate reporting form for annual reports
21 CFR 1010 - 1050, requiring certification to FDA radiation safety performance standards
21 CFR 807, requiring manufacturer registration and device listing, and
21 CFR 807, 812 and 814, requiring medical device clearance or approval

If you have any questions, contact us at (301) 796-5710.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health